

**TRANSLATION**

**PATENT COOPERATION TREATY**  
**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
 (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>D3-A0310P</b>	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. <b>PCT/JP2005/000705</b>	International filing date (day/month/year) <b>20.01.2005</b>	Priority date (day/month/year) <b>22.01.2004</b>
International Patent Classification (IPC) or national classification and IPC <b>C12N15/86, C12N5/10 // (C12N15/86, C12R 1:92), (C12N5/10, C12R1:19)</b>		
Applicant <b>DNAVEC RESEARCH INC.</b>		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:
<input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
<input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
<input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2005/000705

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following which is the language of a translation furnished for the purposes of: \_\_\_\_\_

international search (Rule 12.3 and 23.1(b))

publication of the international application (Rule 12.4)

international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

the international application as originally filed/furnished

the description:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:

nos. \_\_\_\_\_ as originally filed/furnished

nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19

nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:

sheets \_\_\_\_\_ as originally filed/furnished

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_

the claims, nos. \_\_\_\_\_

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (specify): \_\_\_\_\_

any table(s) related to sequence listing (specify): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages \_\_\_\_\_

the claims, nos. \_\_\_\_\_

the drawings, sheets/figs \_\_\_\_\_

the sequence listing (specify): \_\_\_\_\_

any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2005/000705

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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## 1. Statement

Novelty (N)	Claims	<u>2-7, 10-28</u>	YES
	Claims	<u>1, 8, 9</u>	NO
Inventive step (IS)	Claims	<u>2, 4, 10-15, 20-23</u>	YES
	Claims	<u>1, 3, 5-9, 16-19, 24-28</u>	NO
Industrial applicability (IA)	Claims	<u>1-28</u>	YES
	Claims		NO

## 2. Citations and explanations (Rule 70.7)

Document 1: J. Virol., Vol. 77, No. 11 (2003), pages 6419 to 6429

Document 2: The EMBO J., Vol. 21, No. 19 (2002), pages 5141 to 5150

Document 3: J. Virol., Vol. 76, No. 18, (2002), pages 9284 to 9297

1. The invention set forth in 1, 8 and 9 lacks novelty and does not involve an inventive step in the light of document 1 cited in the international search report.

Document 1 sets forth a method of producing the Sendai virus vector which is a negative strand RNA virus vector, wherein (i) nucleic acid lacking the M protein gene which is a type of envelope protein of negative strand RNA virus, and (ii) the expression of said nucleic acid are induced by cytomegalovirus enhancer and chicken  $\beta$ -actin promoter, and said virus vector.

Therefore the invention set forth in claims 1, 8 and 9 is understood to be the same as the invention set forth in document 1.

2. The invention set forth in claims 3, 5 to 7, 16 to 19

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
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and 24 to 28 does not involve an inventive step in the light of documents 1 and 2 cited in the international search report.

Document 2 sets forth a method of producing a Sendai virus vector, which is a negative strand RNA virus vector, wherein mammalian animal cell strains which constantly express T7RNA polymerase are used to induce negative strand RNA virus genome RNA and the expression of said RNA under the control of a promoter, and mammalian animal cells which maintain said virus vector.

The invention set forth in documents 1 and 2 relates to Sendai virus vectors. That being the case, it would be easy for a person skilled in the art to conceive of applying the cytomegalovirus enhancer and chicken  $\beta$ -actin promoter set forth in document 1 as the functional nucleic acid (promoter, etc.) which controls the expression of RNA, in the invention set forth in document 2.

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**Supplemental Box Relating to Sequence Listing****Continuation of Box No. I, item 2:**

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
  - a. type of material  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material  
 in written format  
 in computer readable form
  - c. time of filing/furnishing  
 contained in the international application as filed  
 filed together with the international application in computer readable form  
 furnished subsequently to this Authority for the purposes of search and/or examination  
 received by this Authority as an amendment\* on \_\_\_\_\_
2.  In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

\* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."